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V6

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/297,519 05/03/99 MIDOUX

P 410.015

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EXAMINER

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NGUYEN, D

ART UNIT	PAPER NUMBER
1633	7

DATE MAILED: 08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/297,519

Applicant

Midoux et al.

Examiner

Dave Nguyen

Group Art Unit  
1633

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 20-44 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 20-44 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 20 and 21 have been amended; Claims 1-19 have been canceled; and claims 22-44 have been added by the preliminary amendment filed on July 23, 1999.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 20-39, drawn to a polymeric conjugate comprising substituted monomers having free NH<sub>3</sub><sup>+</sup> groups, methods of transfecting cells by using the polymeric conjugate as a carrier, are classified in class 435, 320.1, and subclass 455.
- II. Claims 41 and 42, drawn to DNA vaccine against influenza, and method of using the vaccine to produce a protective effect in a warm-blooded animal from influenza, are classified in class 514, subclass 44.
- III. Claim 43, are directed to a method of using a polymeric conjugate comprising substituted monomers having free NH<sub>3</sub><sup>+</sup> groups and a DNA encoding a corrective gene to treat any congenital or acquired metabolic deficiency in warmed blood animal, are classified in class 514, subclass 44.
- IV. Claim 44, drawn to a method of using a polymeric conjugate comprising substituted monomers having free NH<sub>3</sub><sup>+</sup> groups and a DNA encoding an anti-tumor protein or product to treat a tumor in warm-blooded animals, are classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Invention I, and inventions II-IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, polymeric carrier of Invention I are not limited for use in each of the DNA therapy claimed in Inventions II, III,

and IV, and can be clearly used in any other invention as set forth in Invention II, III, and IV. In addition, the polymeric carrier can also be used for enhancing gene delivery in cultured cells and in diagnostic assays.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II, III, and IV are directed to materially different methods and distinct goals, e.g., each invention of the respective group comprises materially distinct steps that would generate distinct functions and effects. For example, the invention I employs a DNA that is asserted to generate a therapeutic effect in the treatment of an Influenza infection. However, the invention of Invention III, for example, is drawn to a gene therapy method of using any DNA that exhibits a therapeutic effect in the treatment of any congenital or acquired metabolic deficiency in any warm-blooded animal, wherein any administration route is employed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, it would be unduly burdensome for the examine to search and consider patentability of all the presently pending claims. Thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 304-0196.



Dave Nguyen

Patent Examiner

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